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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/505,854	05/03/2012	Regina Goralczyk	BHD-4662-2197	5907

23117 7590 12/13/2016

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ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
12/13/2016	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte REGINA GORALCZYK,
HASAN MOHAJERI, and ANNIS O. MAYNE-MECHAN

Appeal 2015-004457
Application 13/505,854
Technology Center 1600

Before DONALD E. ADAMS, ULRIKE W. JENKS, and
DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This appeal under 35 U.S.C. § 134(a) involves claims 1–3 and 6–8 (Final Act. 1). Examiner entered rejections under 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

STATEMENT OF THE CASE

Appellants disclose a "nutraceutical composition or food compositions comprising lutein and/or zeaxanthin to improve certain selective memory functions, such as associative learning, associative

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[1] Appellants identify the real party in interest as "DSM IP Assets B.V." (Br. 2).

memory, learning and memory under stress, and spatial (place) learning"

(Spec. 1: 5–8). Claims 1 and 2 are representative and reproduced below:

> 1. A method of enhancing an aspect of memory in a healthy individual, wherein the aspect of memory is selected from the group consisting of:
>
> associative memory, spatial memory and memory under stress comprising:
>
> administering a composition consisting of: a) an effective amount of either lutein
>
> or the combination of lutein and zeaxanthin; and b) an appropriate carrier; and
>
> observing the enhanced associative memory, spatial memory or memory under stress.

(Br. 10.)

> 2. A method of enhancing learning and memory under stress comprising:
>
> administering a composition consisting of: a) a stress related learning and
>
> memory enhancing effective amount of either lutein or the combination of lutein and zeaxanthin; and b) an appropriate carrier; and
>
> observing the enhanced learning and memory under stress.

(*Id.*)

The claims stand rejected as follows:

Claims 1–3 and 6 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Romero[2] and Snyder.[3]

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[2] Romero et al., US 2006/0205826 A1, published Sept. 14, 2006.

[3] J. S. Snyder et al., *A ROLE FOR ADULT NEUROGENESIS IN SPATIAL LONG-TERM MEMORY*, 130 NEUROSCIENCE 843–852 (2005).

Claims 7 and 8 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Romero, Snyder, and Better Nutrition.[4]

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 1. Appellants define the term "healthy" as "the subject is not suffering from any conditions which impair his/her mental health, i.e. is not suffering from conditions characterized by a deterioration in memory such as dementia, Alzheimer's disease or the like, depression, or other psychotic conditions which affect memory and learning such as schizophrenia" (Spec. 5: 20–23; *see* Ans. 4).

FF 2. Appellants define the term "[t]reatment" as "encompass[ing] . . . prevention" and the term "[p]revention" as

> not limited to the complete absence of symptoms in the future, but is intended to include: lessening of the risk that an individual or a population will exhibit a symptom, lessening the symptoms associated with a particular condition, decreasing the time of onset of a particular condition, lessening the severity of a condition, and decreasing the likelihood that an asymptomatic individual will show a condition in the future.

(Spec. 5: 9–14.)

FF 3. Romero discloses the

> [a]dministration of carotenoids[, such as lutein and other carotenoids,] provide a prophylactic and/or therapeutic effect to

[4] *Seeing is Believing!*, BETTER NUTRITION 27 (Source From Google Books-Better Nutrition, Nutritional Specialties, Inc., Anaheim, CA) (2004).

> subjects[, including humans,] who are . . . at risk to develop cognitive decline or other neurological effects, such as diabetic complications, especially those related to neural tissues like retinopathy, peripheral neuropathy and central nervous system.

(Romero, Abstract; *id.* ¶¶ 1 and 12; *see id.* at 6: claims 10–12; *see* Ans. 3; Ans. 4 ("Romero's subjects include subjects who are at risk to develop cognitive decline (e.g. healthy aged adults, diabetic patients)").

FF 4. Romero discloses that "[d]iabetes mellitus correlates with several brain disturbances, including hypersensitivity to stress, cognitive impairment, increased risk of stroke and dementia. Within the central nervous system, the hippocampus is considered a special target for alterations associated with diabetes" (Romero ¶ 54).

FF 5. Romero discloses that "[a]lthough a proper glycemic control is desirable to reduce the development of diabetic complications, it is not sufficient to prevent them completely, the results herein, allow us to propose lutein as a coad[j]uvant treatment of central nervous system complications in diabetes" (Romero ¶ 58; *see also* Muriach,[5] Abstract ("[a]lthough a proper glycemic control is desirable in preventing the development of diabetic complications, it is not sufficient to prevent them completely. Lutein could be an appropriate coadjuvant treatment for the changes observed in this study")).

FF 6. Examiner relies on Snyder to disclose "that [] adult hippocampal neurogenesis has been linked to learning and long-term memory [] and adult neurogenesis is associated in the formation and/or consolidation of long

[5] María Muriach et al., *Lutein effect on retina and hippocampus of diabetic mice*, 41 FREE RADICAL BIOLOGY & MEDICINE 979–984 (2006).

term, hippocampus dependent, spatial memories" (Ans. 3, citing Snyder, Abstract and 851: col. 1, last paragraph, ll. 1–3).

FF 7. Examiner finds that the combination of Romero and Snyder fail to disclose the administration of lutein "as a capsule or in an amount as claimed" and relies on Better Nutrition to make up for the foregoing deficiency in the combination of Romero and Snyder (Ans. 5; *id.* (Examiner finds that "Better Nutrition [discloses] lutein as a daily supplement sold as capsules comprising 10 mg lutein")).

ANALYSIS

The combination of Romero and Snyder:

Based on the combination of Romero and Snyder, Examiner concludes that, at the time Appellants' invention was made, it would have been prima facie obvious "to have administered a composition comprising lutein to enhance spatial memory in healthy individuals," within the scope of Appellants' claimed invention, as suggested by the combination of Romero and Snyder (Ans. 3–4). In this regard, Examiner concludes that "[i]t would have been obvious to add a pharmaceutical carrier to a drug compound for easy administration, absorption and to administer the drug by different routes" (Ans. 4).

We find no error in Examiner's prima facie case of obviousness. Romero discloses the

> [a]dministration of carotenoids[, such as lutein and other carotenoids,] provide a prophylactic and/or therapeutic effect to subjects[, including humans,] who are . . . at risk to develop cognitive decline or other neurological effects, such as diabetic

> complications, especially those related to neural tissues like retinopathy, peripheral neuropathy and central nervous system.

(FF 3.) In this regard, Romero discloses that "[d]iabetes mellitus correlates with several brain disturbances, including hypersensitivity to stress, cognitive impairment, increased risk of stroke and dementia. Within the central nervous system, the hippocampus is considered a special target for alterations associated with diabetes" (FF 4). Snyder discloses, *inter alia*, that spatial memories are hippocampus dependent (FF 6). Therefore, in combination, Romero and Snyder suggest the administration of an effective amount of lutein to produce a prophylactic effect in subjects, which includes humans, with diabetes mellitus who are at risk of developing cognitive decline, which correlates with, *inter alia*, hypersensitivity to stress and hippocampus alterations affecting, *inter alia*, spatial memories (FF 3–4 and 6). As Examiner makes clear, Romero's disclosure of the prophylactic treatment of diabetic patients who are at risk of developing complications associated with diabetes, which includes an aspect of memory associated with memory under stress, reads on Appellants' definition of a healthy individual, i.e., an individual with diabetes mellitus who is not suffering from cognitive decline or any conditions which impair his/her mental health (*see* FF 3; *cf.* FF 1).

Claim 1:

As Examiner explains, there is no requirement that a reference, such as Romero, exemplify all the embodiments that fall within the scope of reference's disclosure (*see* Ans. 7). Therefore, we are not persuaded by Appellants' contention that "Romero does not demonstrate any benefits in

giving lutein to *healthy* individuals" (Br. 5; *cf.* FF 3 (wherein Romero discloses a prophylactic treatment)).

For the foregoing reasons, we are not persuaded by Appellants' contention that the diabetic mice used in Romero's studies are not representative of healthy subjects and associated arguments regarding Muriach, which Appellants characterize as a "publication [that] appears to be the journal article containing the same experiments [involving diabetic mice] as appear in the Romero" (Br. 5–6; *see* FF 5). In this regard, we recognize, but are not persuaded by, Appellants' contention that "Muriach found that there was no significant difference seen in the water maze test between *any* of the test groups" and corresponding extrapolation that "based on the disclosures in Muriach [], an ordinarily skilled person would not have any reasonable expectation of success when administering lutein to untreated healthy mice" (Br. 5–6). Regardless of whether the diabetic mice in Romero's exemplification are healthy, as that term is defined in Appellants' Specification, Appellants' claimed invention encompasses the prophylactic treatment of diabetes patients who are not experiencing diabetes associated complications (*see* Br. 10; FF 1–2; *see* FF 4 (wherein Romero discloses the type of complications that may arise in diabetic patients)). Romero discloses the administration of lutein for the prophylactic treatment of diabetic patients (FF 3–4; *cf.* FF 5 (wherein Romero and Muriach both recognize that lutein is an appropriate coadjuvant treatment for complications associated with diabetes)).

Appellants failed to establish an evidentiary basis on this record to support a conclusion that the prophylactic administration of a composition comprising lutein, as suggested by the combination of Romero and Muriach,

to healthy individuals at risk of develop cognitive decline (i.e. individuals with diabetes mellitus who are not suffering from cognitive decline or any conditions which impair mental health) will not necessarily result in enhancing an aspect of memory (such as associative memory, spatial memory or memory under stress) in those patients. In sum, Appellants' have, at best, discovered a new benefit of an old process, which cannot render the old process patentable. *See In re Huai-Hung Kao*, 639 F.3d 1057, 1071 (Fed. Cir. 2011); *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990).

Claims 2 and 3:

As discussed above, Romero discloses the administration of lutein for the prophylactic treatment of diabetic patients who are at risk of developing cognitive decline, which includes learning and memory under stress and/or spatial learning and memory deficiencies (FF 3–6; *cf.* FF 2 (wherein Appellants define treatment as including a prophylactic treatment)). Therefore, for the reasons discussed above, we are not persuaded by Appellants' contentions that the combination of Romero and Snyder fails to suggest Appellants' claimed invention.

The combination of Romero, Snyder, and Better Nutrition:

Based on the combination of Romero, Snyder, and Better Nutrition, Examiner concludes that, at the time Appellants' invention was made, it would have been prima facie obvious "to use lutein, 10 mg capsules[, as suggested by Better Nutrition,] in" the method suggested by the combination of Romero and Snyder (*see* Ans. 5–6). In this regard, Examiner reasons that

the "[a]dminstration of a 10 mg capsule daily would roughly correspond to a daily dosage of 0.15 mg/day or two 10 mg lutein capsules would correspond to 0.28 mg/day," which "falls within the claimed dosage range of [Appellants' claim 8]" (Ans. 6).

Appellants do not address the combination of Romero, Snyder, and Better Nutrition, therefore, we are compelled to affirm the rejection of record.

CONCLUSION OF LAW

The preponderance of evidence relied upon by Examiner supports a conclusion of obviousness.

The rejection of claims 1–3 under 35 U.S.C. § 103(a) as unpatentable over the combination of Romero and Snyder is affirmed. Claim 6 is not separately argued and falls with claim 1.

The rejection of claim 7 under 35 U.S.C. § 103(a) as unpatentable over the combination of Romero, Snyder, and Better Nutrition is affirmed. Claim 8 is not separately argued and falls with claim 7.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED